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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,765	10/03/2005	Kazuyuki Oku	OKU10	5593

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EXAMINER	
ISSAC, ROY P	

ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,765	OKU ET AL.	
	Examiner	Art Unit	
	Roy P. Issac	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/12/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is a 371 of PCT/JP04/04079, filed 03/24/2004 and claims priority under 35 U.S.C §119 (a)-(d) and 365(c) to foreign application Japan 2003-100408 filed 04/03/2003. A certified copy of foreign priority application in Japanese is received. A translation of the PCT application is received, but not that of the foreign application.

Applicants' preliminary amendment filed 10/03/2005 in which claims 4-6 and 8-16 were amended is acknowledged. Claims 1-16 are currently pending are examined on the merits herein.

Claim Objections

Claim 8 is objected to because of the following informalities: Claim 8 recites the phrase "means the regulation the amount" which appears to be missing "of" in the phrase. Appropriate correction is required.

Claim 8 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 8 adds the limitation "where lipid regulating means the regulation the amount of lipids in said living body". It is not clear whether the applicant is invoking the means-plus-function language here or trying to define the phrase "lipid regulating". In case of a definition, it doesn't appear to further limit claim 1 from which it depends. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the lowering cholesterol or lowering the amount of triglycerides in blood plasma does not reasonably provide enablement for regulating lipid or regulating the amount of lipids in human body or regulating the metabolism of lipoproteins. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The skilled artisan would view that the recitation, **regulating** the amount of lipids in human body or regulating the metabolism of lipoproteins, would reasonably encompass both increasing as well as lowering the amount of lipid in blood and lowering as well as increasing the metabolism.

The instant claims are drawn to a composition for regulating skin and regulating the metabolism of lipoproteins. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight

factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The instant invention pertains to compositions for regulating, i.e., encompassing both both increasing as well as lowering the amount of lipid in blood and lowering as well as increasing the metabolism.

The relative skill of those in the art: The relative skill of those in the art is high.

The presence or absence of working examples: In the instant case, **no** working examples are presented in the specification as filed showing how to use the composition herein to show how to increase as well as decrease the amount of lipid in blood or lower as well as increase the metabolism.

The lack of working examples is a critical and crucial factor to be considered, especially in cases involving an unpredicatable and undeveloped art. See MPEP § 2164.

The predictability or lack thereof in the art and the quantity of experimentation necessary:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art would recognize that the recitation encompasses thousands of compositions with varying effects and unknown side effects. As such, each composition will need to be individually evaluated for activity.

The skilled artisan would view that, regulating, encompassing both increasing as well as decreasing the amount of lipid in blood or loweing as well as increasing the metabolism is highly unpredictable since the skilled artisan would not understand how the same compound or agent could increase and decrease the level of lipid in blood or how the same composition can increase as well as decrease the rate of metabolism.

Delzenne et. al. reports that dietary triacylglycerols (lipids) are transported from lymph to the blood as chylomicrons and then hydrolyzed by lipoprotein lipase. (Am. J. Nutr 2001, 73, 456S-8S; PTO-892). Delzenne identifies fatty acid synthase as the most sensitive to nutrients and hormones. Delzenne further notes that the addiction of oligofructose and other nondigestable carbohydrates to the diets of rats can decrease lipogenesis in the liver by lowering the activity of key enzymes regulated only through modifications of gene expression. (Conclusions). It is not clear how the instant

compositions can regulate enzymes that are only regulated through gene expression. Furthermore, a compound that can act to lower the activity of an enzyme is very unlikely to be able to increase the activity of the same enzyme. Nothing in the specification shows an ability of the instant compositions to both lower as well as increase the amount of lipids in blood. Furthermore, nothing in the specification shows an ability for the instant compositions to increase as well as lower the rate of metabolism.

The skilled artisan would view that regulating t the amount of lipids in human body or regulating the metabolism of lipoproteins in a subject including increasing as well as lowering the amount of lipid in blood and lowering as well as increasing the metabolism.

Genentech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the *Wands* factors as discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in ***undue experimentation*** to achieve methods of regulating the condition of skin.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation, "derivative" in these claims render claims herein indefinite. The recitations, "derivative" of the compounds are not clearly defined in the specification. Hence, one of ordinary skill in the art could not ascertain and interpret the metes and bounds of the patent protection desired as to "derivative" of compounds herein. One of ordinary skill in the art would clearly recognize that the recitations "{→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→}, and/or a saccharide derivative thereof" as well as derivatives of the classes of compounds listed in claims 3 and 7 would read on any those compounds having any widely varying groups that possibly substitute the compounds.

Any significant structural variation to a compound would be reasonably expected to alter its properties; e.g., physical, chemical, physiological effects and functions. Thus, it is unclear and indefinite as to the "derivatives" of compounds herein encompassed thereby.

Claims 6-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9 recites "0.1% by weight or more" in

reference to the amount of cyclic tetrasaccharide. The lack of an upper limit renders the claim indefinite.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 4, the phrase "such as" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5 and 9-14 of copending Application No. 10/565,069. Although the conflicting claims are not identical, they are not patentably distinct from each other because this application claims a lipid-regulating agent comprising a cyclic tetrasaccharide represented by the formula {→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→}, and/or its saccharide-derivative(s) as an effective ingredient, and the '069 application claims an accelerator for mineral absorption, which comprises an effective ingredient cyclic tetrasaccharide represented by {→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→}, and/or a saccharide derivative thereof. Note that, the recitations "a lipid-regulating agent", "used for improving a lifestyle-related disease", "used for one or more objects of inhibiting the increase of weight, decreasing total cholesterol, decreasing LDL-cholesterol, regulating the metabolism of lipoproteins, inhibiting the accumulation of lipids, regulating the metabolism of bile acids, and improving the intestinal function" are considered intended uses of the compositions claimed. Note that it is well settled that "intended use" of a composition or product, e.g., "a lipid-regulating agent", will not further limit claims drawn to a composition or product, so long as the prior art discloses the same composition comprising the same ingredients in an effective amount, as the instantly claimed. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Thus, claims 1-16 are deemed anticipated by claims 1-5 and 9-14 of the co-pending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1 and 8-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 8 of copending Application No. 10/495,975. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '975 application claims compounds and composition comprising cyclic tetrasaccharide of claim 1. As discussed above, the recitations "a lipid-regulating agent", "used for improving a lifestyle-related disease", "used for one or more objects of inhibiting the increase of weight, decreasing total cholesterol, decreasing LDL-cholesterol, regulating the metabolism of lipoproteins, inhibiting the accumulation of lipids, regulating the metabolism of bile acids, and improving the intestinal function" are considered intended uses of the compositions claimed. An intended use of a composition is not considered to be further limiting the composition claim. Thus, claim 1 is deemed anticipated by claims 1-3 and 8 of the co-pending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Kubolta et. al. (WO 01/90338, Publication Date 11/29/2001; PTO-892;). English Equivalent, U.S. Patent No. 7,192,746 is used *in lieu* of translation.

Kubolta et. al. discloses the synthesis of the cyclotetrasaccharide, cyclo {→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→}. (Abstract, Example A-1 to A-5, Columns 55-58). Kubolta further discloses a composition comprising said cyclic tetrasacchirde, (100 parts by weight), mineral, sodium chloride and potassium chloride, magnesium sulfate in preparation for fluid diet. (Example B-18, Column 65, lines 20-40). Kubolta further discloses sodium L-ascorbate, vitamin E and trehalose in composition comprising cyclic tetrasaccharide. (Example B-18, Column 65, lines 20-40). Kubolta further discloses several examples of compositions comprising said cyclostetrasaccharide and one or more of the ingredients of claims 2-14 herein. (Examples B1-B25; Columns 60-68). Note that, the recitations "a lipid-regulating agent", "used for improving a lifestyle-related disease", "used for one or more objects of inhibiting the increase of weight, decreasing total cholesterol, decreasing LDL-cholesterol, regulating the metabolism of lipoproteins, inhibiting the accumulation of lipids, regulating the metabolism of bile acids, and improving the

intestinal function" are considered intended uses of the compositions claimed. As discussed above, "intended use" of a composition or product, will not further limit claims drawn to a composition or product, so long as the prior art discloses the same composition comprising the same ingredients in an effective amount, as the instantly claimed.

As such, claims 1-16 are deemed anticipated by Kubolta et. al.

Claims 1, 2, 5-7 and 12-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Cote GL et. al. (U.S. Patent No. 5,786,196; PTO-1449 dated 2/12/07).

Cote et. al. discloses the a composition comprising cyclo {→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→6)-α-D-glucopyranosyl-(1→3)-α-D-glucopyranosyl-(1→} and other saccharides, and their separation using chromatography. (Abstract, Column 5 lines 58-Column 25). As discussed above, the recitations "a lipid-regulating agent", "used for improving a lifestyle-related disease", "used for one or more objects of inhibiting the increase of weight, decreasing total cholesterol, decreasing LDL-cholesterol, regulating the metabolism of lipoproteins, inhibiting the accumulation of lipids, regulating the metabolism of bile acids, and improving the intestinal function" are considered intended uses of the compositions claimed. An intended use of a composition is not considered to be further limiting the composition claim. Thus, claims 1, 2, 5-7 and 12-16 are deemed anticipated by Cote et. al.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy P. Issac whose telephone number is 571-272-2674. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

4/30/07

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